

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN,

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

Case No. 1:14-cv-01614-AJT-JFA

Hon. Anthony J. Trenga  
Hon. John F. Anderson

**MEMORANDUM IN SUPPORT OF  
PLAINTIFFS' MOTION TO COMPEL  
PRODUCTION OF DOCUMENTS**

JANINE ALI,

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

Case No. 1:14cv-01615-AJT-JFA

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## **INTRODUCTION**

Plaintiffs Gilda Hagan-Brown and Janine Ali move to compel production of documents from Defendant Eli Lilly and Company (“Lilly”) relating to Lilly’s promotion of Prozac in the 1990s involving antidepressant withdrawal. Plaintiffs allege that Lilly actively promoted Prozac to doctors and patients as being a superior antidepressant because of its favorable withdrawal profile. However, when Prozac’s patent expired, and Lilly sought to fill the revenue void with its new antidepressant Cymbalta, Lilly took an opposite approach—instead of being upfront and forthright about Cymbalta’s withdrawal risk, Lilly crafted a misleading label and deliberately avoided researching the issue. (Complaint ¶¶ 17-19, 21, 28(g), Exh. 1<sup>1</sup>*available at Ali*, 14-cv-01614, Dkt.1.) Thus, Lilly’s promotion of Prozac and antidepressant withdrawal in the 1990s is relevant for at least three reasons. First, it indicates that Lilly had knowledge about the importance of antidepressant withdrawal in marketing. Second, it suggests that Lilly’s conduct in promoting Cymbalta was done with fraudulent intent and / or reckless disregard for the truth. Third, it shows Lilly had the capability of properly researching the issue of antidepressant withdrawal and conveying that information to doctors. Lilly’s refusal to produce documents responsive to these requests prior to 2001 is inappropriate. Plaintiffs seek an order compelling their production.

## **BACKGROUND**

### **I. Lilly Specifically Used the Withdrawal Issue to Promote Prozac as Being a Superior Antidepressant to Paxil and Zoloft in the 1990s**

Cymbalta is an antidepressant in a class known as selective serotonin and norepinephrine reuptake inhibitors (“SNRIs”). (*Id.* ¶¶ 9-10.) This lawsuit centers on a phenomenon called

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<sup>1</sup> All exhibits cited in this memorandum can be found as exhibits to the Declaration of R. Brent Wisner filed concurrently with this brief.

“withdrawal”—the physical and mental effects patients suffer when they stop Cymbalta. (*Id.* ¶ 15.) It is widely accepted that an antidepressant’s withdrawal risk is in large part associated with the drug’s half-life, i.e., the amount of time for half of a drug to leave a patient’s system. (*Id.*) The shorter a drug’s half-life, the faster the drug leaves the patient’s body. (*Id.*) This rapid depletion, in turn, leads to more frequent and pronounced withdrawal symptoms. (*Id.*)

Much of the research about the relationship between half-life and withdrawal was conducted by Lilly as part of Lilly’s efforts to bolster sales of the antidepressant Prozac in the 1990s. (*Id.* ¶¶ 17-19.) In December 1996, Lilly sponsored a “closed symposium” titled “SSRI Discontinuation Events.” (*See Excerpts of Antidepressant Discontinuation Syndrome: Update on Serotonin Reuptake Inhibitors*, 58 J. CLINICAL PSYCHIATRY Suppl. 7 (1997), Exh. 2.) The symposium was followed by a medical journal supplement, also sponsored by Lilly, which contained eight articles concerning antidepressant withdrawal, written by a number of Lilly consultants. (*Id.* at 4.) According to Michael Detke, M.D., the former Global Medical Director of Cymbalta and Prozac at Lilly, several of the authors who published articles as part of this Lilly-funded symposium ended up participating on Lilly’s Global Advisory Board for Cymbalta. (Excerpts of the Deposition of Michael Detke, M.D. (“Detke Depo.”) at 47:23-51:18, Exh. 4 (noting how several authors identified in the journal supplemental worked closely with Dr. Detke and were on Lilly’s Global Advisory Board for Cymbalta).) The symposium and journal articles differentiated the withdrawal risks of various antidepressants on the market at the time and noted that an antidepressant’s propensity to induce withdrawal reactions is associated, in large part, to a drug’s half-life. (*See Excerpts from the Journal of Clinical Psychiatry Supplement 7 (1997)*, Exh. 3.) In this context, Lilly’s first blockbuster antidepressant, Prozac (generically known as fluoxetine), which has a considerably long half-life, was touted as being far better with respect to

withdrawal) than the shorter half-life drugs, Paxil (paroxetine), Zoloft (sertraline), Luvox (fluvoxamine) and Effexor (venlafaxine). (*Id.*; see Complaint ¶¶ 17-19, Exh. 1.)

Subsequently, a study was published in 1998 by Lilly consultants Jerrold Rosenbaum and Maurizio Fava, along with three Lilly employees, comparing Prozac to Paxil and Zoloft. (Jerrold Rosenbaum et al, Selective, *Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial*, 44 BIOLOGICAL PSYCHIATRY 2, 77-87 (1998), Exh. 5.) The study was sponsored and funded by Lilly. (Admission No. 42 (pg. 19), Exh. 6; see also Letter to Dr. Maurizio Fava from Barney Krebs at FAVA-001-\*002, Exh.7.) In the study, the authors “hypothesized that interruption of fluoxetine treatment would be associated with fewer discontinuation-emergent adverse events than interruption of sertraline or paroxetine treatment, based on fluoxetine’s longer half-life.” (Exh. 5 at \*78 (pg. 1).)

The study was conducted using a 43-item checklist of potential withdrawal reactions wherein patients were affirmatively asked whether they had experienced such symptoms over the previous week (after discontinuing whatever antidepressant they were taking as part of the study). (*Id.*; see *Clinical Report Form, Discontinuation Emergent Signs and Symptoms* at FAVA-003-\*004, Exh. 8.) The conclusion of the study was that withdrawal reactions were “associated with the emergence of new somatic and psychological symptoms in patients treated with paroxetine and to a lesser degree sertraline, with few symptoms seen with fluoxetine.” (Exh. 5 at \*78 (pg. 1).)

This is in contrast to Lilly’s clinical trials of Cymbalta (an antidepressant with the second shortest half-life, next to Effexor) where withdrawal reactions were only recorded if patients volunteered one or more of the characteristic reactions associated with withdrawal. (See David G. Perahia, et al., *Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in*

*Patients with Major Depressive Disorder*, 89 J. Affective Disorders 207-212, 211 (2005), Exh. 9 (“The main limitation of this review is that [withdrawal reactions] were assessed by means of spontaneous reports rather than a symptom checklist. The latter might be expected to produce higher incidence rates.”).)

Plaintiffs allege that Lilly conducted this research as part of a marketing effort to position Prozac in the competitive antidepressant marketplace. (Complaint ¶¶ 17-19, Exh. 1.) Recent testimony from Dr. Detke, the former Medical Director for Cymbalta and Prozac, indicates that this allegation has merit:

Q. What was the Prozac promotion dealing with discontinuation symptoms?

[objection omitted]

A. I wasn’t directly involved with Prozac promotion, but my general understanding is that the relatively fewer D[iscontinuation] E[mergent] A[verse] E[vent]s with Prozac compared to most of the other drugs in the class was promoted.

Q. So Lilly was promoting Prozac as having fewer discontinuation symptoms than Paxil and other drugs in that category?

[objection omitted]

Is that correct?

A. I think that’s essentially accurate.

(Detke Depo. at 182:24-183:13, Exh. 4.) Dr. Detke’s testimony confirms that Lilly did, in fact, engage in some form of marketing effort to promote Prozac and its withdrawal profile. As described below, this discovery dispute centers on obtaining documents relating to Lilly’s marketing efforts relating to Prozac and withdrawal to understand how Lilly used the withdrawal issue in its marketing and promotion of Prozac.

## II. Recent Discovery Indicates that Lilly's Marketing Efforts Relating to Prozac and Withdrawal Influenced the Way Lilly Viewed and Considered Cymbalta Withdrawal

The Complaint alleges that:

Lilly should have been aware of the significance of antidepressant withdrawal, because Lilly had previously researched and publicized the issue in connection with its antidepressant Prozac. Because Prozac has an extremely long half-life relative to other antidepressants, the length of time it takes for a person's body to fully eliminate Prozac from the system provides a built-in gradual tapering of sorts, so that withdrawal symptoms from Prozac are relatively infrequent. Prozac's main competitors in the 1990s, Zoloft and Paxil, had shorter half-lives, and Lilly engineered a campaign to differentiate Prozac from its competitors on this basis, funding clinical studies of antidepressant withdrawal and coining the term "antidepressant discontinuation syndrome."

(Complaint ¶ 17, Exh. 1.) Recent discovery confirms this allegation. For instance, a 2002 email by a senior Lilly research physician concerning Cymbalta (before Cymbalta was approved for marketing) states: "Discontinuation symptoms are a big deal in MDD (*thanks to ourselves with Prozac promotion*)."

(Email Correspondence at CYM-01813088, Exh. 10 (emphasis added).)

The researcher recommends, in light of Lilly's promotion of Prozac, "we would propose gradual tapering" in the Cymbalta label. (*Id.*)

Similarly, Lilly recently produced an unredacted version of an email exchange between various Lilly executives in 2003 concerning Cymbalta's withdrawal risk.<sup>2</sup> In the email

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<sup>2</sup> Previously, undersigned counsel represented to the Court that Lilly was inappropriately redacting documents. This email is a perfect example. The email was originally produced with redactions. (See Email at CYM-01873415, Exh. 11.) A line from an email from Dr. David Perahia and Dr. Detke's response were redacted without explanation. (*Id.*) Recently, however, after Plaintiffs' counsel threatened to go to the Court, Lilly produced an unredacted version of the email. (See Email at CYM-R-01873415, Exh. 12.) Apparently, Lilly redacted Dr. Perahia's and Dr. Detke's references to Prozac marketing efforts. What makes these redactions so egregious, however, is that, before producing the unredacted document, Lilly filed a motion *in limine* in the Cymbalta cases in California seeking to exclude any evidence of Lilly's promotion of Prozac, arguing that Plaintiff's claim "that Lilly, armed with knowledge of the risk of antidepressant discontinuation symptoms, crafted the discontinuation language in Cymbalta's label to increase sales . . . are unsupported[.]" (See Motion in Limine to Bar Evidence or Argument Related to Prozac at 10, *Herrera v. Eli Lilly and Company*, 13-CV-2702, Dkt. 157

exchange, Dr. David Perahia, a researcher for Lilly and the lead author of the Perahia article, expressed concern about Cymbalta's withdrawal risk and the liability it posed:

I must confess to being a little uncomfortable [sic] about the whole discontinuation thing. Maybe it's more of a UK specific issue, but paroxetine [Paxil] is taking a fearsome battering in the media over here at the moment, and a significant part of that is discontinuation-related stuff. ***It's clear that duloxetine has a significant DESS [discontinuation-emergent signs and symptoms] liability*** (on abrupt discontinuation, admittedly, but how much taper data do we have yet ?), and the perception will be further reinforced by our short [half-life] which is seen by many as being directly linked (*partly due to the work Lilly did around Prozac's long t1/2 [half-life] . . .*).

... If we're not careful, ***the environment is set for this to blow up in our faces*** unless we're proactive about it.

(Email at CYM-R-01873415, Exh. 12 (emphasis added).) Lilly scientists were acutely aware that having a withdrawal risk profile similar to Paxil posed "significant DESS liability" and could "blow up in [their] faces" due, in part, to Lilly's promotion of Prozac's short half-life and favorable withdrawal profile. (*Id.*) In response, Dr. Detke dismisses the issue, explaining that he "was told by someone who was then a ***Prozac sales rep in the US that they tried to increase the importance of DESS [Discontinuation Emergent Signs and Symptoms] and half-life in prescribing decisions[.]***" (*Id.* (emphasis added).) Thus, medical personnel at Lilly were specifically referencing and discussing Lilly's promotion of Prozac and antidepressant withdrawal in considering what actions, if any, Lilly would do to be "proactive" about

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(C.D. Cal.).) In other words, Lilly concealed information supporting Plaintiff's claims and then argued to exclude such evidence because Plaintiff's lacked sufficient support. But Lilly's shenanigans are not limited to the California cases. Lilly produced this unredacted document as part of a document production on the afternoon of April 28, 2015—a few hours after Dr. Detke's deposition had already started. This meant that Plaintiffs were prevented from asking Dr. Detke about his unredacted email response. (*See* Detke Depo. at 189:4-193:14, Exh. 4 (Dr. Detke explaining that he does not remember what was discussed in the redacted portion of the email).) It appears Lilly timed its production of the unredacted document (along with many others) in such a way so as to prevent Plaintiffs from questioning Dr. Detke. When Plaintiffs' counsel raised this issue at the end of Dr. Detke's deposition, Lilly's counsel balked and objected to allowing any further deposition of Dr. Detke. (*Id.* at 270:3-271:17.)



Cymbalta's DESS [discontinuation-emergent signs and symptoms] liability." (*Id.*) Lilly's promotion of Prozac and withdrawal *directly* affected how Lilly viewed and acted with regard to Cymbalta withdrawal.

### **III. The Discovery Dispute**

On April 15, 2015, Lilly was served with Plaintiffs' Second Set of Requests for Production containing four requests for production of documents. (Exh. 13.) Three of the requests relate to Lilly's promotion of the antidepressant Prozac and antidepressant withdrawal. (*Id.* at 8.)

**2ND SET, RFP NO. 1:** Please produce the results, summaries, and/or presentations concerning market surveys and/or focus groups for PROZAC that mention, measure, or refer to WITHDRAWAL or discontinuation symptoms.

**2ND SET, RFP NO. 2:** Please produce all marketing plans, market analyses, pricing studies, patient segmentation studies, conjoint studies / discrete choice studies, and/or any form of marketing evaluation of PROZAC that mention or discuss the issue of WITHDRAWAL or discontinuation symptoms.

**2ND SET, RFP NO. 3:** Please produce all marketing and/or sales documents that discuss, mention, or compare the WITHDRAWAL profile of Prozac to other antidepressants, including but not limited to CYMBALTA, Zoloft, Effexor, Paxil, Celexa, and Lexapro.

(*Id.*) Following the hearing on April 16, 2015, the parties discussed these three document requests. (Wisner Decl. ¶ 25.) Plaintiffs' counsel explained the purpose of the document requests, the type of information being sought, and explained that the requests did not contemplate a massive document production. (*Id.*)

In an email follow-up, Lilly's counsel requested more specific information. (Email Exchanges at 3-4, Exh. 14.) Plaintiffs' counsel responded, clarifying the scope of the document requests. Plaintiffs' counsel explained that:

The first two Prozac requests seek documents wherein Lilly conducted marketing surveys, focus groups, segmentation studies, message testing, etc., and one of the issues mentioned or discussed was risk of discontinuation symptoms / withdrawal. To put this in context, Lilly produced several marketing studies and

summaries about Cymbalta which showed that the risk of withdrawal was important to pricing and prescribing decisions. *See, e.g.*, [bates references omitted]<sup>3</sup> That production was not major—only about a 100 documents. We are looking for the same about Prozac, but have limited the search to the issue of withdrawal[.]

(*Id.* at 1-2.) With regard to the third request, Plaintiff’s counsel explained:

This request seeks (1) Prozac marketing plans that the discuss promotion of Prozac’s superior withdrawal profile as way to position Prozac as being superior to competing antidepressants / increase sales/prescriptions, and (2) sales aids / “slim-jims” / brochures used by Lilly’s sales reps to compare Prozac’s withdrawal profile to other antidepressants. This does not contemplate a massive production[.]

(*Id.* at 2.)

On April 29, 2015, Lilly served its objections to Plaintiffs’ discovery requests (Exh. 15 at 2-5) and on May 15, 2015, served its responses (Exh. 16 at 2-3.) Subsequently, on May 18 and 19, 2015, Lilly made two document productions consisting of fifty-two documents. (Wisner Decl. ¶¶ 26-27.) These documents, however, (1) did not contain any documents prior to 2001,

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<sup>3</sup> Two examples of these types of documents are presented in Exhibits 22 and 23. Exhibit 22 is a document entitled “Cymbalta U.S. Strategic Pricing Study: Exploratory Qualitative Market Research Conducted with Payers, Physicians, and Patients” and involves the results of a survey conducted in 2002 with physicians, patients, and third-party payors to evaluate what factors would influence Lilly’s pricing strategy for Cymbalta. (Exh. 22 at CYM-02786217-\*219). The survey revealed that “[p]hysicians are doubtful Cymbalta can compete at any price premium to Effexor XR” and that one of the three factors that “could justify or warrant consideration of premium pricing relative to Effexor XR” was “[a] significant decrease in the rate of and severity of withdrawal / discontinuation syndrome[.]” (*Id.* at CYM-02786305.) The documents goes on to explain that of the “product attributes that justify a premium price over other antidepressants . . . Minimization of withdrawal syndrome is also seen as important.” (*Id.* at CYM-02786310.) Exhibit 23 is a document titled “Patient Segmentation Study” and contains the results of a survey conducted in 2004 to determine, among other things, the “[c]urrent motivators to prescribe anti depressants [.]” (Exh. 23 at CYM-02784115-\*117.) The survey revealed that of the “Factors Influencing Doctor’s Selection of an Antidepressant” the factor of “Avoid dependence / withdrawal issues” was the highest rated. (*Id.* at CYM-02784163.) The survey explains that “‘Avoid dependence / withdrawal issues’ is one of the important factors in selecting an antidepressant. . . This can be used an opportunity for Cymbalta.” (*Id.* at CYM-02784183.) These document are exemplars of the types of marketing document being sought related to Prozac and antidepressant withdrawal.

(2) did not contain any marketing plans for Prozac, and (3) did not contain any sales aids used by Lilly sales representatives to promote Prozac. (Wisner Decl. ¶ 28.)<sup>4</sup>

Recognizing these deficiencies, Plaintiffs' counsel contacted Lilly to determine why certain documents were missing. (Email at 1, Exh. 17.) This prompted a phone discussion with counsel on May 19, 2015. (Wisner Decl. ¶ 29.) During the conversation, Plaintiffs' counsel learned that Lilly's search for documents was limited to a "SinglePoint" marketing database, used by Lilly to organize its marketing documents. (*Id.*) Based on Lilly's representations about the SinglePoint database, Lilly is able to conduct a simple Boolean search of the documents and produce whichever documents were responsive. (*Id.*) The SinglePoint database, however, only goes back to 2001 and does not contain marketing documents from the 1990s—the years when Lilly was actively promoting Prozac and antidepressant withdrawal. (*Id.*) During the phone call, Lilly's counsel also explained that there is no centralized database of Prozac marketing plans, sales aids, or market surveys, and that producing such documents would require Lilly to search various Lilly's personnel emails for appropriate documents. (Wisner Decl. ¶ 30.) Lilly's counsel explained that such a search was simply too burdensome. (*Id.*)

In an effort to reach some compromise on the issue, Plaintiffs counsel proposed, in lieu of producing documents, to conduct a Rule 30(b)(6) deposition on the issue of Prozac marketing and antidepressant withdrawal or allow written discovery related to the issue in the form of interrogatories and requests for admission. (Wisner Decl. ¶ 31.) Lilly's counsel stated he would

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<sup>4</sup> The productions were not complete and did not contain the type of information being sought. There was, however, one document that is relevant to this motion, which is attached as Exhibit 21. The document is titled "Prozac Pyramid Positioning / Message Development Research" and reflects the results of market research conducted in 2000. (Exh. 21 at CYM-02989903.) The document reflects a recommendation that Lilly, in promoting Prozac, should "consider expanding on the idea that Prozac's long half-life prevents discontinuation syndrome, making direct comparisons to Paxil and Zoloft." (*Id.* at CYM-02989906.) Thus, in 2000 Lilly was being advised to promote Prozac's favorable withdrawal profile in its marketing to physicians.

consider the proposal, but on May 20, 2015, rejected the proposal. (Email at 2, Exh. 18.) The following day, Plaintiffs' counsel indicated that a motion to compel would be forthcoming. (*Id.* at 1.)

### **LEGAL STANDARD**

Discovery "is broad in scope and freely permitted." *Carefirst of Md., Inc. v. Carefirst Pregnancy Centers, Inc.*, 334 F.3d 390, 402 (4th Cir. 2003). "In essence, a party is entitled to any nonprivileged information that is relevant to a claim or defense in the matter." *Humanscale Corp. v. CompX Int'l, Inc.*, No. 3:09-CV-86, 2009 WL 5091648, at \*1 (E.D. Va. Dec. 24, 2009) (citing Fed. R. Civ. P. 26(b)). Relevant information need not be admissible at trial, it simply must appear "reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1); *Wu v. Tseng*, 2007 WL 4143077, at \*3 (E.D. Va. 2007). "[T]he burden of proof is with the party objecting to the discovery to establish that the challenged production should not be permitted." *Singletary v. Sterling Transp. Co.*, 289 F.R.D. 237, 241 (E.D. Va. 2012).

### **ARGUMENT**

#### **I. Plaintiffs' Targeted Document Requests Are Reasonably Calculated to Lead to Relevant Information**

From the beginning, Plaintiffs alleged that Lilly's experience with marketing and promoting Prozac's favorable withdrawal profile in the 1990s proved that Lilly was aware of the importance of fully disclosing an antidepressant's risk of withdrawal with Cymbalta. (Complaint ¶¶ 17-19, Exh. 1.) Plaintiffs have also alleged that Lilly deliberately avoided measuring the risks associated with Cymbalta withdrawal based, in part, on Lilly's experience marketing this very issue with Prozac. (*Id.* ¶¶ 21, 82(d).) These allegations are central to Plaintiffs' causes of action.

With regard to Plaintiffs negligence (*id.* ¶¶ 37-43) and failure-to-warn claims (*id.* ¶¶ 53-68), Plaintiffs must show that Lilly knew, or had reason to know, that its conduct in warning

about Cymbalta's risk of withdrawal was deficient or insufficient. *Owens-Corning Fiberglas Corp. v. Watson*, 243 Va. 128, 134, 413 S.E.2d 630, 634 (1992) (“[M]anufacturer has a duty to warn only if it knows or has reason to know that its product is dangerous.”); (see Complaint ¶¶ 48, 62, 65, Exh. 1). Evidence that Lilly researched the withdrawal issue and broadly disseminated it as part of its promotion of Prozac shows that Lilly had knowledge of the importance of the withdrawal risk and had *a reason to know* that its “1% or greater” warning for Cymbalta was insufficient. Furthermore, evidence that Lilly conducted itself one way with Prozac, using rigorous methods to evaluate withdrawal, and a different way with Cymbalta, is further evidence that Lilly failed to properly satisfy its duty as a pharmaceutical manufacturer.

With regard to Plaintiffs' constructive fraud claim (Complaint ¶¶ 69-77, Exh. 1), Plaintiffs must establish that Lilly “represented as true what is really false, in such a way as to induce a reasonable person to believe it, with the intent that the person will act upon this representation.” *Baker v. Elam*, 883 F. Supp. 2d 576, 580 (E.D. Va. 2012) (quoting *Mortarino v. Consultant Eng'g Servs., Inc.*, 251 Va. 289, 295, 467 S.E.2d 778, 782 (1996)). Evidence that Lilly knew that the likelihood of withdrawal risk would influence a prescribing doctor's decision to prescribe an antidepressant, as shown by Lilly's marketing efforts relating to antidepressant withdrawal in 1990s with Prozac, goes directly to the issue of intent. It makes it more likely that Lilly's conduct in minimizing the risks of withdrawal was done with the requisite intent that prescribers rely upon the misleading Cymbalta warning.

With regard to Plaintiffs' actual fraud claim (Complaint ¶¶ 69-77, Exh. 1), Plaintiffs must establish that Lilly acted intentionally or with “reckless abandon and disregard for the truth” in warning about the frequency, severity, and duration of Cymbalta withdrawal. *Hitachi Credit Am. Corp. v. Signet Bank*, 166 F.3d 614, 628 (4th Cir. 1999). And, under Virginia law, “willful

nondisclosure of a material fact” may constitute actual fraud. *Id.* Thus, evidence that Lilly acted one way with Prozac, i.e., actively researched and broadly distributed information about Prozac’s withdrawal profile to physicians, especially as it compared to competing antidepressants, and acted very differently with Cymbalta, i.e., downplayed Cymbalta’s withdrawal risks and deliberately avoided conducting probing research on the issue, goes directly to whether Lilly’s conduct in promoting Cymbalta was intentional or done with “reckless abandon and disregard for the truth.”

Plaintiffs’ document requests, thus, are reasonably calculated to lead to discoverable information. These three requests are laser-focused on obtaining documents evidencing Lilly’s promotion and marketing conduct with regard to Prozac solely on the issue of withdrawal. Plaintiffs are not seeking some massive production of documents, just the handful of documents related to Lilly’s (1) market research on the issue of withdrawal (2ND SET, RFP NOS. 1, 2), (2) Lilly’s general marketing plans related to withdrawal (2ND SET, RFP NOS. 2, 3), and (3) the sales pieces used by Lilly to promote Prozac’s favorable withdrawal profile (2ND SET, RFP NO. 3).<sup>5</sup> In sum, these document requests are reasonably calculated to lead to relevant information under Fed. R. Civ. P. 26(b)(1) and, thus, Lilly should be compelled to produce responsive documents.

## **II. Lilly’s Reasons for Not Complying with Plaintiff’s Discovery Requests Are Without Merit**

Lilly will likely make two arguments as to why it should not be compelled to produce these documents—relevance and burdensomeness. Neither of these reasons carries much weight.

First, Lilly will argue, as it has in other Courts, that discovery related to Prozac is

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<sup>5</sup> These documents would also be relevant to establishing that Lilly could have engaged in the same conduct with regard to Cymbalta to better educate physicians about Cymbalta’s risk of withdrawal.

inappropriate because this lawsuit concerns Cymbalta and there is no evidence that either plaintiff or their physicians relied upon Prozac promotion in deciding to ingest or prescribe Cymbalta. This argument is without merit. As discussed above, the requested documents are relevant to several of Plaintiffs' claims as evidence of prior knowledge, intent, and feasibility. Moreover, as discussed in the Background, Section II, there is evidence that Lilly's conduct with regard to Prozac directly influenced Lilly's conduct with regard to Cymbalta—there is no “Chinese Wall” within Lilly between Prozac and Cymbalta. Several of the people who worked on Prozac were directly involved with Cymbalta: Dr. Detke was the global medical director for both Cymbalta and Prozac (*see* Detke Depo. at 28:18-30:11, Exh.4); Dr. Sharon Hoog, who was a medical advisor for Cymbalta, started off as a clinical research physician on Prozac and published numerous articles on both Prozac and Cymbalta<sup>6</sup> (*see* Excerpts of Deposition of Sharon Hoog (“Hoog Depo.”) at 16:5-17:6, 69:12-74:10, Exh. 19); and several of the researchers hired by Lilly to conduct withdrawal research on Prozac ended up being members of the Cymbalta Global Advisory Board at Lilly (*see* Detke Depo. at 47:23-51:18, Exh. 4). Any attempt by Lilly to suggest that its conduct related to Prozac withdrawal has nothing to do with its conduct regarding Cymbalta withdrawal is belied by the record. Indeed, when Lilly attempted to make this argument in seeking a motion for a protective order to avoid producing clinical trial data related to Prozac in a case in the Central District of California, the Magistrate Judge rejected the argument:

Plaintiffs' theory appears to be that Lilly previously sponsored studies on symptoms associated with stopping the use of SSRI's and SNRI's. These studies compared at least Prozac, Paxil and Zoloft, which are SSRI's, and Effexor, which is an SNRI.

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<sup>6</sup> Indeed, according to Dr. Hoog's deposition, she played a significant role in organizing research on Prozac withdrawal in 1997. (See Hoog Depo. at 85:18-99:10.)

These studies showed a correlation between the frequency of withdrawal symptoms and the half-life of the drug. Moreover, Lilly touted its drug Prozac as having a relatively long half-life and suggested that the long half-life would be expected to result in less frequent appearance of withdrawal symptoms.

Now Lilly is marketing Cymbalta which has a relatively short [ ] half-life. Lilly sponsored a study regarding withdrawal symptoms of Cymbalta that used a different method of obtaining indications of withdrawal symptoms than used in the earlier studies. Specifically, rather than systematic monitoring with a checklist to record symptoms, it relied on spontaneous reports from study subjects. Plaintiff contends this method resulted in lowering reporting of withdrawal symptoms.

...

I also find that it is at least arguable that Lilly's knowledge of withdrawal risks as demonstrated by earlier studies played a part in its evaluation of Cymbalta's withdrawal risks and could be relevant to the punitive damage issue.

So, based on those findings, my tentative would be that the Plaintiff is entitled to the information they're seeking.

(Transcripts of Proceedings: Defendant's Motion for Protective Order, *Carter v. Eli Lilly and Company*, 13-CV-2700, *Hexum v. Eli Lilly and Company*, 13-CV-2701, *Herrera v. Eli Lilly and Company*, 13-CV-2702, at 6:16-7:25 (Sept. 9, 2014), Exh. 20.) The same reasoning applies here. These document requests are specifically tailored to obtain potentially relevant documents involving Lilly's knowledge and intent with regard to antidepressant withdrawal. They are, thus, discoverable.

Second, Lilly will likely argue that producing responsive documents would be too burdensome because Lilly would have to search old email accounts of Lilly personnel to obtain the records. This argument is unsupported. Having Lilly do an electronic search for emails to find relevant documents is hardly unreasonable or needlessly burdensome.<sup>7</sup> This is commonplace in complex pharmaceutical cases. Moreover, as explained above, these requests

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<sup>7</sup> Although counsel never discussed this issue, Plaintiffs believe that Lilly already has databases containing this information arising out of litigation involving Prozac in the 1990s and 2000s.



do not contemplate a massive document production. Plaintiff envisions a few hundred documents, at most, relating to Lilly's marketing plans, marketing research, and sales aids related to Prozac and antidepressant withdrawal.

**CONCLUSION**

For the forgoing reasons, Plaintiffs respectfully request that this Court grant Plaintiffs' motions to compel, and order Lilly to produce documents responsive to Plaintiffs' 2ND SET, RFP NOS. 1, 2, and 3.

Dated: May 22, 2015

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Peter Miller, hereby certify that on the 22<sup>nd</sup> day of May, 2015, a true copy of the foregoing MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF DOCUMENTS was filed electronically with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to the following:

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